

## DECLARATION OF CONFORMITY

We hereby declare that the CE marked products manufactured by Peregrine Surgical Ltd., specified in the annexed products list, conform to the product(s) covered by the “CE Marking of Conformity Certificate”, reference number:

86255 CE 01 issued on April 20, 1998, renewed on April 22, 2016 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Number 0344, in accordance with Annex V in combination with Annex VII of the “EC-Directive”, the Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC, concerning medical devices.

In addition, we ensure and declare that the CE marked products manufactured by Peregrine Surgical Ltd., as mentioned and falling within Class IIa by Rules 6, 9 and 11, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V in combination with Annex VII of the EC-Directive. The conformity of the assurance system set out in Annex V in combination with Annex VII, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2003, Quality System Certificate with reference number: 160770.01 issued on March 9, 1998 and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers disposable ophthalmic fiber optics, hand instruments, vitreous cutters, and laser probes as specified in the product list (Annex 1) to this declaration, and is valid for all products concerned bearing the CE marking and manufactured after April 1, 1998 at the following site:

Peregrine Surgical Ltd.  
51 Britain Drive  
New Britain, PA 18901  
USA

Authorized Representative:

Advena Ltd  
Pure Offices  
Plato Close  
Warwick  
CV34 6WE  
United Kingdom

Issued: 6/3/16  
New Britain, PA



Jayne Guthrie  
Director, QA/QC

Annex 1: Product List /Product Line with Relative Features

# PRODUCT LIST

## Infusion Sleeves

PRODUCT NAME		PRODUCT CODE		DATE APPROVED FOR CE MARK
Infusion Sleeve		PD505.06		April 18, 2005

## PRODUCT LIST

### Disposable Ophthalmic Fiber Optics

PRODUCT NAME	PRODUCT CODE	DATE APPROVED FOR CE MARK
20GA Light Pipe	PD100.00	March 16, 1999
20GA Side Irrigating Light Pipe	PD100.01	March 16, 1999
20GA End Irrigating Light Pipe	PD100.02	March 16, 1999
20GA Straight Pick Light Pipe	PD100.03	March 16, 1999
20GA 45 Degree Pick Light Pipe	PD100.04	March 16, 1999
20GA Monofilament Light Pipe	PD100.06	March 16, 1999
20GA Ryan Pick Light Pipe	PD100.07	June 5, 2003
20GA Wide Angle Light Pipe	PD100.09	March 16, 1999
20GA Tapered Diffusion Probe	PD100.10	March 16, 1999
20GA 2-Function Light Pipe	PD100.11	March 16, 1999
20GA 3-Function Light Pipe	PD100.12	September 24, 2001
20GA Bipolar Pick Light Pipe	PD100.13	September 24, 2001
20GA Tapered Diffusion Probe	PD100.14	May 1, 2002
20GA Tapered Diffusion Probe	PD100.14B	June 24, 2011
20GA Tapered Diffusion Probe	PD100.14S	June 24, 2011
20GA Tapered Diffusion Probe	PD100.14SB	June 24, 2011
20GA Bipolar Pick Light Pipe	PD100.15	November 19, 2004
23GA Light Pipe	PD100.23	July 28, 2006
20GA Light Pipe	PD101.00	March 16, 1999
20GA 45 Degree Pick Light Pipe	PD101.04	March 16, 1999
20GA Monofilament Light Pipe	PD101.06	March 16, 1999
20GA Ryan Pick Light Pipe	PD101.07	June 5, 2003
20GA Wide Angle Light Pipe	PD101.09	March 16, 1999
20GA Tapered Diffusion Probe	PD101.10	March 16, 1999
20GA 2-Function Light Pipe	PD101.11	March 16, 1999
20GA Tapered Diffusion Probe	PD101.14	May 1, 2002
23GA Light Pipe	PD101.23	July 28, 2006
20GA Light Pipe	PD102.00	March 16, 1999
20GA 45 Degree Pick Light Pipe	PD102.04	March 21, 2003
20GA Monofilament Light Pipe	PD102.06	March 16, 1999
20GA Ryan Pick Light Pipe	PD102.07	June 5, 2003
20GA Wide Angle Light Pipe	PD102.09	March 16, 1999
20GA Tapered Diffusion Probe	PD102.10	March 16, 1999
20GA 2-Function Light Pipe	PD102.11	March 16, 1999
20GA 3-Function Light Pipe	PD102.12	March 21, 2003
20GA Tapered Diffusion Probe	PD102.14	May 1, 2002
23GA Light Pipe	PD102.23	July 28, 2006
20GA Light Pipe	PD103.00	March 16, 1999
20GA Ryan Pick Light Pipe	PD103.07	June 5, 2003
20GA Wide Angle Light Pipe	PD103.09	March 21, 2003
20GA 3-Function Light Pipe	PD103.12	March 21, 2003
20GA Tapered Diffusion Probe	PD103.14	May 1, 2002
23GA Light Pipe	PD103.23	July 28, 2006
20GA Light Pipe	PD104.00	June 5, 2003
20GA Ryan Pick Light Pipe	PD104.07	June 5, 2003
20GA Tapered Diffusion Probe	PD104.14	June 5, 2003
23GA Light Pipe	PD104.23	July 28, 2006